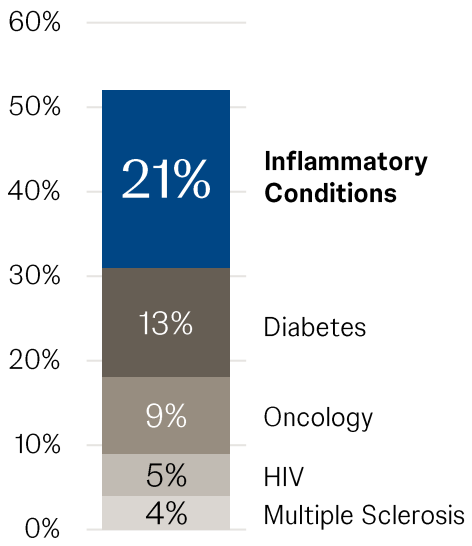
EVIDENCE & VALUE SUMMARY: TREMFYA® (guselkumab)

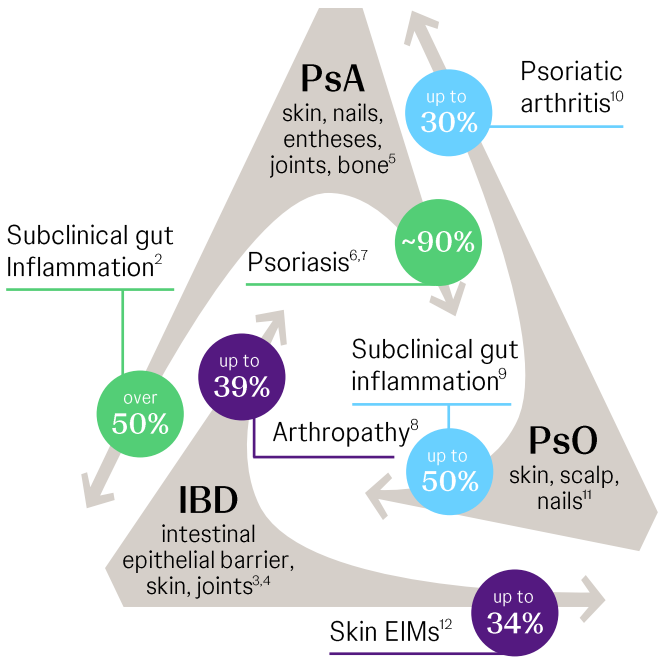
Inflammatory conditions have a significant impact on the patient and the United States healthcare system

Immunologic therapies present the highest cost burden for commercial plans

Top 5 therapy classes for commercial plans, by percent of total PMPY spending, 2020[1a]



Inflammatory conditions are complex and may present with extra-intestinal, extra-articular, and extra-cutaneous manifestations



These conditions impact many people in the United States

	Prevalence[a]	Moderate-to-severe disease	Biologic-treated
PsO	7,500,000[13]	20%[14]	51%[15]
PsA	2,250,000[10,13b]	80%[15]	62%[16]
CD	1,011,000[17]	58%[18]	44%[19]
UC	1,253,000[17]	40%[20]	16%[19]

Patients with PsO have a **4x** higher prevalence of IBD, with the highest risk in the population with both PsO and PsA[21]

Psoriatic diseases are complex with high unmet need and costs

In patients with PsO who develop PsA, skin manifestations may develop up to a decade before musculoskeletal, although musculoskeletal manifestations may occur at any time[10]

Radiologic damage in PsA is similar to that seen in patients with RA[10,22c]

Patients with PsO or PsA may also experience subclinical gut inflammation[2,9]

In a survey of patients with PsO and/or PsA[23]:

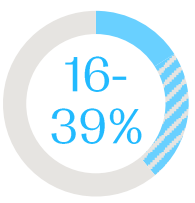
56%
experienced at least a moderate impact on quality of life

52%
screened positive for potential major depressive disorder

High economic burden[24-27]:

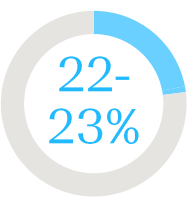
$9,591
PsO annual indirect cost due to total work productivity loss per patient

Among employed



experience work disability

Unemployed



Inflammatory bowel diseases are complex with high unmet need and costs

UC: Colon and the rectum, typically appears in a continuous pattern[28]

CD: Anywhere in the GI tract from the mouth to the anus; may appear in patches[29]

Up to 40% of patients with CD have at least 1 EIM, and common EIMs include mucocutaneous, musculoskeletal, liver, eye, and urinary tract involvement.[3]

In a survey of patients with UC or CD[30d]:

agreed that symptoms impact most aspects of daily life

experienced anxiety, depression, and/or embarrassment because of IBD

High economic burden[31]:

UC direct and indirect costs in the United States:

$15.5 billion/year

CD direct and indirect costs in the United States:

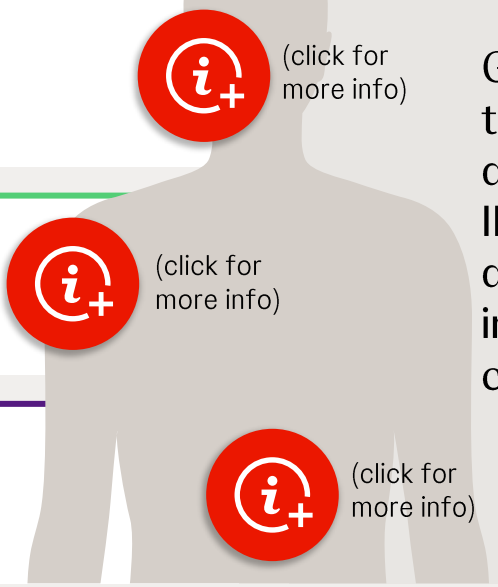
$14.9 billion/year

TREMFYA® is an IL-23i indicated for the treatment of adults with[32e]:

PsO
Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

PsA
Active psoriatic arthritis

UC
Moderately to severely active ulcerative colitis



Guselkumab is the only[f] fully human dual-acting, selective IL-23 inhibitor designed to neutralize inflammation at its cellular source[33-38]

Based on in vitro studies in inflammatory monocyte models. The clinical significance of these findings is unknown.

For additional information, please see TREMFYA® Prescribing Information here.

[a]In the United States. [b]Prevalence of patients with PsO who develop PsA. [c]Based on no difference in the radiographic severity of small joints between patient populations with RA and PsA. [d]Based on a survey of 302 adults with IBD in the United States via MyCrohnsandColitisTeam.com. [e]TREMFYA® dosing for moderate to severe plaque PsO and active PsA: 100mg SC at Weeks 0 and 4, and q8w thereafter. For moderately to severely active UC, induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter or 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. [f]"Only" Based on approved IL-23 inhibitors for active PsA or moderately to severely active UC as of September 2024.

CD, Crohn's disease, EIMs, extraintestinal manifestations; HIV, human immunodeficiency virus; IBD, inflammatory bowel disease, IL-23i, interleukin-23; IV, intravenous; PMPY, per member per year; PsA, psoriatic arthritis; PsO, psoriasis; q4w, every 4 weeks; q8w, every 8 weeks; RA, rheumatoid arthritis; SC, subcutaneous; UC, ulcerative colitis; US, United States.

1. Evernorth. Trend by plan type. Accessed October 28, 2024. https://www.evernorth.com/drug-trend-report/trend-by-plan-type. 2. Scher JU. *J Rheumatol Suppl.* 2018;94;32-35. 3. Levine JS, et al. *Gastroenterol Hepatol (N Y).* 2011;7(4):235-241. 4. Matricon J, et al. *Self Nonself.* 2010;1(4):299-309. 5. Suzuki E, et al. *Autoimmun Rev.* 2014;13(4-5):496-502. 6. Ciocon DH, et al. *Br J Dermatol.* 2007;157(5):850-860.
7. Pennington SR, et al. *Front Med (Lausanne).* 2021;8:723944. 8. Arvikar SL, et al. *Curr Rev Musculoskelet Med.* 2011;4(3):123-131. 9. Sanchez IM, et al. *Curr Derm Rep.* 2018;7:59-74. 10. Mease P, et al. *J Am Acad Dermatol.* 2013;69(5):729-735. 11. Lowes MA, et al. *Annu Rev Immunol.* 2014;32:227-255. 12. Levine JS, et al. *Gastroenterol Hepatol (N Y).* 2011;7(4):235-241. 13. Armstrong A, et al. *JAMA Dermatol.* 2021; 157(8): 1-7. 14. Menter A, et al. *J Am Acad Dermatol.* 2008;58(5):826-850. 15. Data on file. Janssen Biotech, Inc. 16. Kavanaugh A, et al. *Clinical Rheumatology.* 2018;37(8):2275-2280. 17. Lewis J, et al. *Gastroenterology.* 2023: 1-9. 18. Manceur A, et al. *J Med Econ.* 2020;23(10):1092-1101. 19. Yu H, et al. *Aliment Pharmacol Ther.* 2018;47(3);364-370. 2018. 20. Cohen R, et al. *J Med Econ.* 2015;18(6):447-456. 21. Eppinga H, et al. *Inflamm Bowel Dis.* 2017; 23(10):1783-1789. 22. Rahman P, et al. *J of Rheum.* 2001; 28(5):1041-1044. 23. Lebwohl M, et al. *Derm Ther.* 2022;12:61-78. 24. Villacorta R, et al. *Br J Dermatol.* 2020;183(3): 548–558. 25. Kaarela K, et al. *Scand J Rheumatol.* 1987;16:4036. 26. Zhu T, et al. *J Rheumatol.* 2010;37:121420. 27. Tillett W, et al. *Rheumatology (Oxford).* 2012;51(2):275-283. 28. Ye Y, et al. *Inflamm Bowel Dis.* 2020;26(4):619-625. 29. The Crohn's & Colitis Foundation of America. The facts about inflammatory bowel diseases. Updated November 2014. Accessed February 20, 2024. https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. 30. Charabaty A, et al. *Crohn's and Colitis 360.* 2022;4:1-9. 31. Click B, et al. *Inflamm Bowel Dis.* 2020;26(8):1268-1275. 32. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 33. Wojtal K, et al. *PLoS One.* 2012;7(8):e43361. 34. Vos AC, et al. *Gastroenterology.* 2011;140(1):221-230. 35. Louis E, et al. *Aliment Pharmacol Ther.* 2004;19(5):511-519. 36. Abreu M, et al. DDW 2023. Oral Presentation #3856970. 37. Krueger J, et al. ISID 2023. Poster #1591. 38. Bsat M, et al. *Eur J Immunol.* 2020;50(11):1676-1690.

US-SFM-6542 10/24

Johnson&Johnson

TREMFYA® (guselkumab) for adults with moderate to severe plaque psoriasis

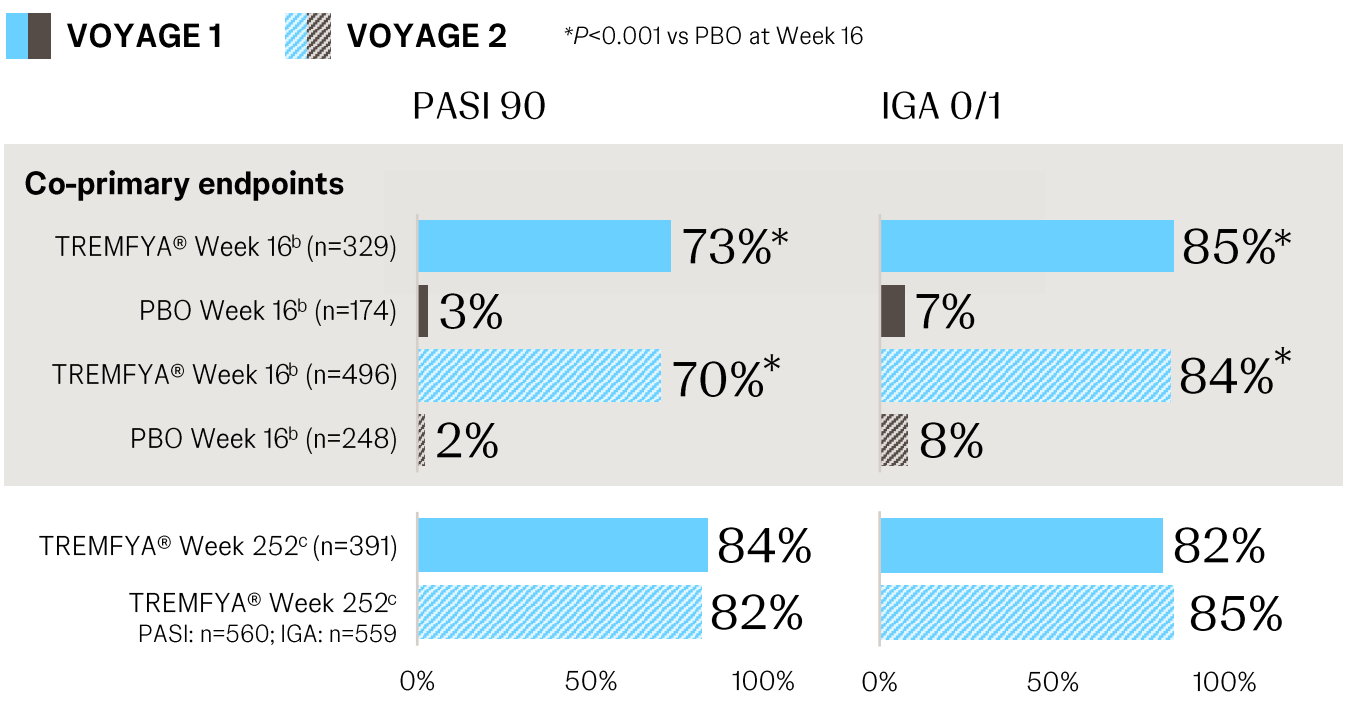
TREMFYA® has established safety and efficacy for adult patients with moderate to severe plaque PsO[a]

Moderate to severe plaque PsO[1-5]

VOYAGE 1 (N=837) and

VOYAGE 2 (N=992) were phase 3, multicenter, double-blind, placebo-controlled, active comparator trials evaluating the efficacy and safety of TREMFYA® vs placebo in adult patients with moderate to severe plaque PsO who were candidates for phototherapy and/or systemic therapy. Co-primary endpoints in both trials were PASI 90 and IGA 0/1 at Week 16.[a]

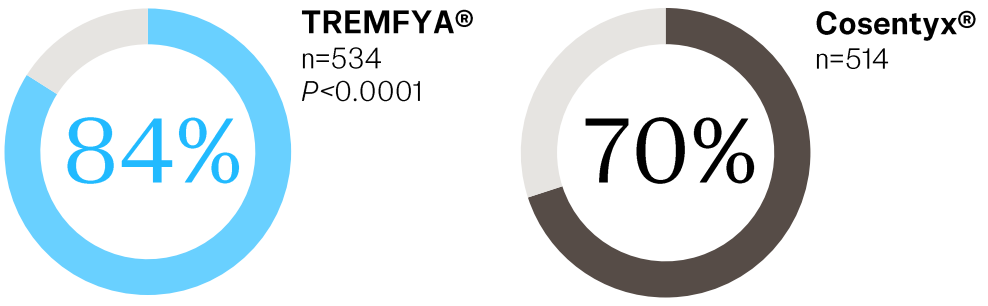
PASI 90 and IGA 0/1 responses achieved and maintained through Year 5



ECLIPSE (N=1048) was a phase 3, double blind, active comparator trial evaluating the efficacy and safety of TREMFYA® 100 mg versus Cosentyx® (secukinumab). The primary endpoint was PASI 90 at week 48 for noninferiority and then superiority tests.[5d]

The proportion of patients in the study who achieved PASI 90 response at Week 48 was greater in the TREMFYA® group than the comparator group

There were no new safety findings observed for either TREMFYA® or Cosentyx® in this study.[5]



Safety data results are established through 5 years in moderate to severe plaque PsO

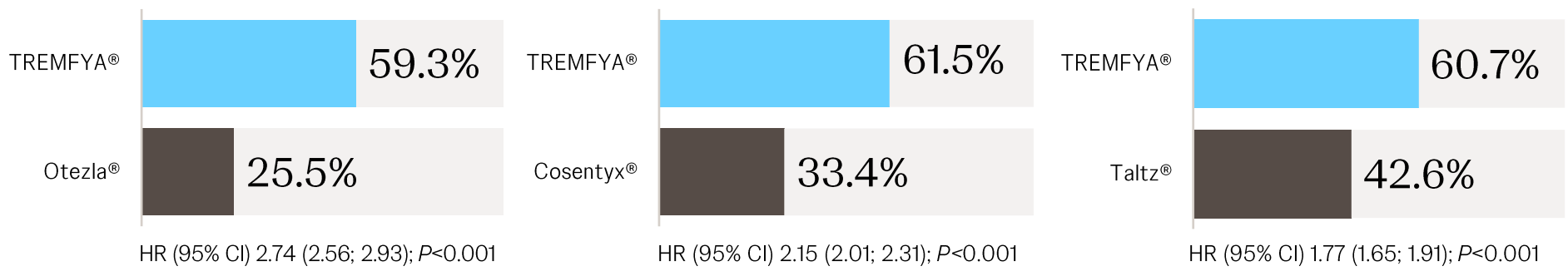
Selected safety profile[1,6]

Please refer to the full Prescribing Information for a complete listing of all adverse events for all indications, including other serious adverse events.

Safety Results From VOYAGE Trials (PsO)	Adverse events		Serious adverse events		Infections		Serious infections	
	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo
Week 16, % [events/100 PYs of follow-up] TREMFYA® n=823, placebo n=422	49.2 [330.1]	46.7 [316.9]	1.9 [6.3]	1.4 [4.7]	23.2 [97.9]	21.3 [86.4]	0.1 [0.4]	0.2 [0.8]
Year 5, events/100 PYs of follow-up, n=1721[e]	149.4	--	5.0	--	60.6	--	0.9	--

TREMFYA® has demonstrated significantly better treatment persistence versus comparators in plaque PsO

Kaplan-Meier persistence probability among real-world patients with moderate to severe plaque PsO at 18 months[7,8f]



Among patients with PsO, TREMFYA® was:

~3× more persistent than Otezla® (apremilast) at 18 months.[g]

~2× more persistent than Cosentyx® (secukinumab) and Taltz® (ixekizumab) at 18 months.[h,i]

Based on a real-world study of Merative™ MarketScan® data in the United States

Future considerations for TREMFYA®: Select ongoing phase 3b trials in PsO

VISIBLE: Adults with skin of color, moderate-to-severe plaque PsO, and/or scalp PsO[9]

SPECTREM: Adults who are bio-naïve with low BSA moderate plaque PsO and special site involvement[10]

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For more information on ongoing trials, go to ClinicalTrials.gov. For additional information, please see TREMFYA® Prescribing Information here.

[a]TREMFYA® dosing for moderate to severe plaque PsO: 100 mg administered subcutaneously at Week 0, 4, and q8w thereafter. [b]Nonresponder imputation. [c]Data from an open-label extension. Treatment failure rules. Includes patients who crossed over from placebo to receive GUS at Week 16. [d]Intent-to-treat population. [e]Includes all patients exposed to TREMFYA® in VOYAGE 1 and VOYAGE 2. [f]Results may not be generalized to the uninsured or patients with noncommercial insurance. Prescription fills do not account for whether medication was taken. Results may be subject to residual confounding. [g]Cohort sizes: TREMFYA® (guselkumab) N=3,379; Otezla® (apremilast) N=10,087. [h]Cohort sizes: TREMFYA® N=3,516; Cosentyx® (secukinumab) N=6,066. [i]Cohort sizes: TREMFYA® N=3,805; Taltz® (ixekizumab) N=4,674.

BSA, body surface area; CI, confidence interval; GUS, guselkumab; HR, hazard ratio; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PBO, placebo; PsO, psoriasis; PYs, patient-years; q8w, every 8 weeks.

1. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. VOYAGE 1 NCT02207231. 3. VOYAGE 2 NCT02207244. 4. Reich K, et al. *Br J Dermatol.* 2021; 1087-1088. 5. Reich K, et al. *Lancet.* 2019;394(10201):831-839. 6. Data on file. Janssen Biotech, Inc. 7. Fitzgerald T, et al. Poster presented at: 2022 Fall Clinical Dermatology Conference: October 20-23 2022; Las Vegas, NV. 8. Zhdanava M, et al. *J Dermatol Treatment.* 2024;35(1):2349658. 9. VISIBLE NCT05272150. 10. SPECTREM NCT06039189.

Johnson&Johnson

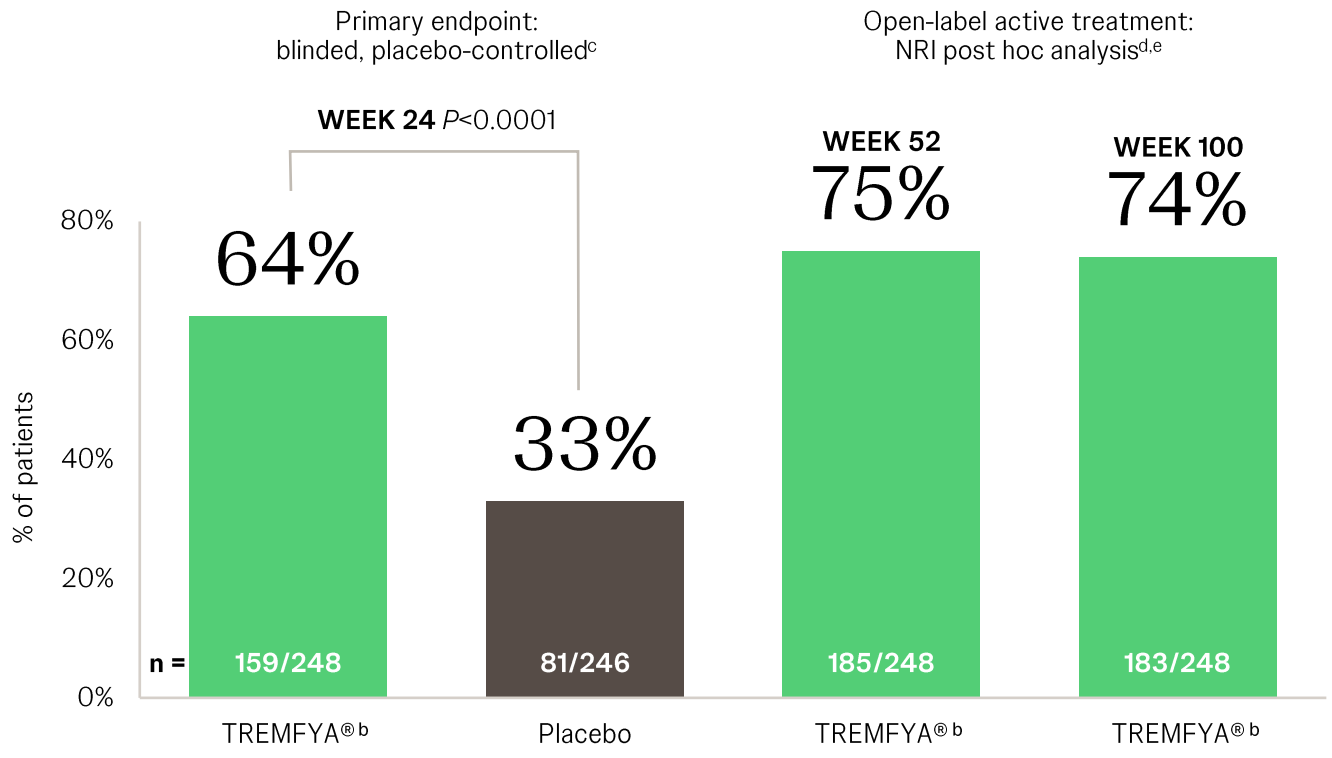
TREMFYA® (guselkumab) for adults with active psoriatic arthritis

TREMFYA® has established safety and efficacy for adult patients with active PsA[a]

Active PsA[1-3]

DISCOVER 1 (N=381; bio-naïve population [69%] and bio-experienced population: ≤2 TNFα inhibitors [31%]) and **DISCOVER 2** (N=739; bio-naïve population) were phase 3, multicenter, double-blind, placebo-controlled trials evaluating the efficacy and safety of TREMFYA® vs placebo in adult patients with active PsA despite standard therapies. The primary endpoint in both trials was ACR20 at Week 24.[a]

Patients had continuous overall improvement in joint response (ACR20) rates through 2 years in DISCOVER 2[b]



DISCOVER 1

ACR20 response rates for TREMFYA®100 mg q8w vs placebo[1,4]:

At 24 weeks:

52% (66/127) vs 22% (28/126); *P*<0.0001

At 52 weeks:

60% (76/127) of patients receiving GUS q8w

Safety data results are established through 2 years in active PsA

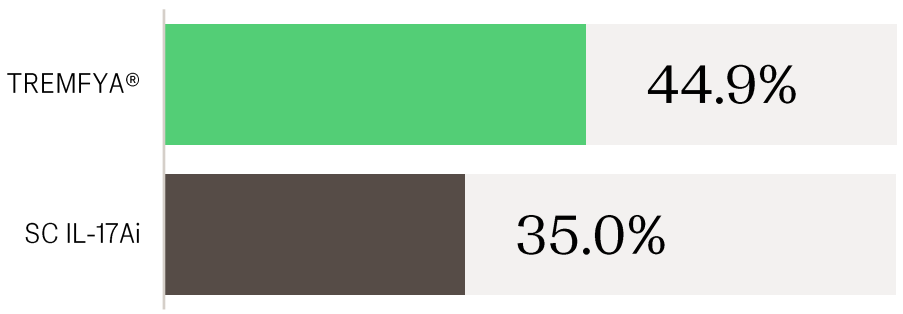
Selected safety profile[1-2,5]

Please refer to the full Prescribing Information for a complete listing of all adverse events for all indications, including other serious adverse events.

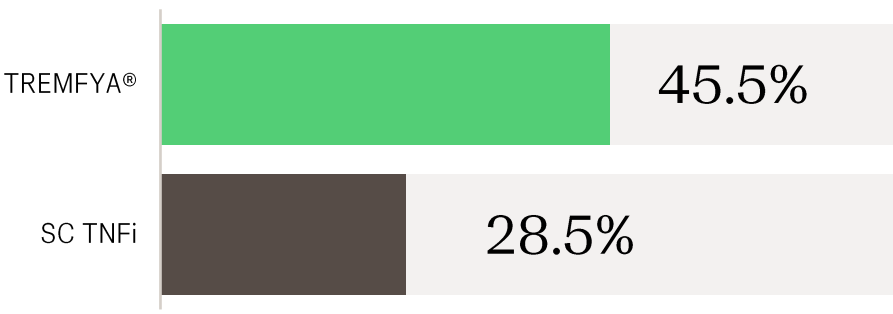
Safety Results From DISCOVER Trials (PsA)	Adverse events		Serious adverse events		Infections		Serious infections	
	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo
Week 24, % [events/100 PYs of follow-up] TREMFYA® n=375, placebo n=372	48.5 [257.3]	47.3 [220.0]	1.9 [4.0]	3.2 [9.3]	19.5 [58.3]	20.7 [58.5]	0.3 [0.6]	0.8 [4.1]
Year 2, events/100 PYs of follow-up, n=248[f]	158.0	--	6.1	--	40.5	--	2.2	--

TREMFYA® has demonstrated significantly better treatment persistence versus comparators in active PsA

Weighted Kaplan-Meier persistence probability among real-world patients with active PsA at 24 months[6,7g]



HR (95% CI) 1.49 (1.29; 1.72); *P*<0.001



HR (95% CI) 2.24 (1.90; 2.64); *P*<0.001

Among patients with PsA, TREMFYA® was:

~1.5× more persistent than subcutaneous IL-17Ai inhibitors, including Cosentyx® and Taltz®.[h,i]

Based on a real-world study of IQVIA™ Health Plan Claims data in the United States.

~2.2× more persistent than subcutaneous TNF inhibitors, including Humira®, Enbrel®, Cimzia®, and SIMPONI®.[i,j,k]

Based on a real-world study of IQVIA™ Health Plan Claims data in the United States.

Future considerations for TREMFYA®: Select ongoing phase 3 and 4 trials in PsA

APEX: Adults who are bio-naïve with active PsA and inhibiting radiographic progression[8]

STAR: Adults who are bio-naïve with active PsA axial disease[9]

SOLSTICE: Adults with active PsA and inadequate response or intolerance to a prior anti-TNFα[10]

The safety and efficacy of the investigational uses of this product have not been determined.
There is no guarantee that the investigational uses listed will be filed with and/or approved for marketing by the FDA.

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For more information on ongoing trials, go to ClinicalTrials.gov. For additional information, please see TREMFYA® Prescribing Information here.

[a]TREMFYA® dosing in active PsA: 100 mg administered subcutaneously at Week 0, 4, and q8w thereafter. [b]Prespecified as-observed analysis from Week 24 to Week 100 from DISCOVER 2 and from Week 24 to Week 52 from DISCOVER 1 are not shown. [c]Patients with missing data were considered nonresponders. [d]The same patients may not have responded at each time point. [e]After Week 24, the study was open label with blinded dosing interval, which may have affected results. [f]DISCOVER 2 only. [g]Results may not be generalized to the uninsured or patients with noncommercial insurance. Data do not ensure treatments are taken as prescribed. Claims data do not provide treatment effectiveness or reasons for discontinuation. Days of supply in pharmacy claims data can be inaccurate due to coverage restrictions. Imputation is a valid approach that is often utilized in claims-based analyses but may lead to misclassifications. [h]sc IL-17Ai agents included Taltz® (ixekizumab) (n=933) and Cosentyx® (secukinumab) (n=1,668). Guselkumab cohort N=849. [i]Propensity score weighting was used to obtain a balanced sample. Weights were estimated using a multivariable logistic regression model. Baseline covariates included several demographic and clinical characteristics. Weighted Cox proportional hazard model was used to compare risk of discontinuation between the cohorts. [j]scTNFi agents (N=2,490) included Humira® (adalimumab) (n=1,742), Enbrel® (etanercept) (n=528), Cimzia® (certolizumab pegol) (n=198), and SIMPONI® (SC golimumab) (n=22). Guselkumab cohort: N=804. [k]Inverse probability weights were used to obtain a balanced sample. Weights were estimated using a multivariable logistic regression model. Weighted Cox proportional hazard model was used to compare risk of discontinuation between the TREMFYA® and SC TNFi cohorts. Models were adjusted for baseline use of bDMARDs. Primary analysis was conducted based on a 2x duration of time between administration per label.

ACR, American College of Rheumatology; bDMARD, biologic disease modifying anti-rheumatic drug; CI, confidence interval; FDA, Food and Drug Administration; GUS, guselkumab; HR, hazard ratio; IL-17Ai, interleukin-17A inhibitor; NRI, nonresponder imputation; PsA, psoriatic arthritis; PYs, patient-years; q8w, every 8 weeks; SC, subcutaneous; TNFα, tumor necrosis factor alpha; TNFi, tumor necrosis factor inhibitor.

1. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. McInnes I, et al. *Arthritis Rheumatol.* 2022;74(3):475-485. 3. Mease P, et al. *Lancet.* 2020; 395:1126-1136. 4. Ritchlin C, et al. *RMD Open.* 2021;7(1):e001457. 5. Data on file. Janssen Biotech, Inc. 6. Mease P, et al. Poster Presented at: 2024 Congress of Clinical Rheumatology West, September 26-29, 2024, San Diego, CA. 7. Mease P, et al. Poster Presented at: 2024 Congress of Clinical Rheumatology West, September 26-29, 2024, San Diego, CA. 8. APEX NCT04882098. 9. STAR NCT04929210. 10. SOLSTICE NCT04936308.

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TREMFYA® (guselkumab) for adults with moderately to severely active ulcerative colitis

QUASAR clinical program

TREMFYA® was evaluated in multicenter, randomized, double-blind, placebo-controlled induction and maintenance studies in adult patients with moderately to severely active UC.[1] The induction study (N=701) randomized patients 3:2 to receive TREMFYA® 200 mg IV q4w or placebo IV.[1,2] The maintenance study (N=568) took TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders[a] and rerandomized 1:1:1[b] to receive TREMFYA® 200 mg SC q4w, TREMFYA® 100 mg SC q8w, or placebo SC.[1,3]

Patient population[1]

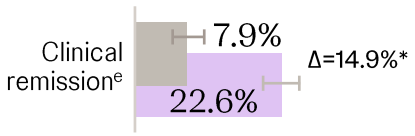
Adults with moderately to severely active UC[c]

Prior inadequate response, loss of response, or intolerance to conventional or advanced therapy

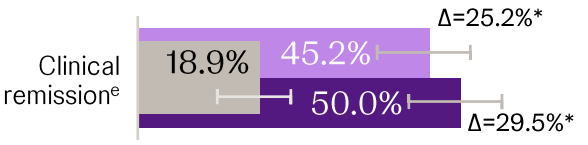
49% of patients had prior inadequate response or intolerance to advanced therapy (TNFi, VDZ, or TOFA)

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC[1,2,4,5d]

Primary endpoint at Week 12

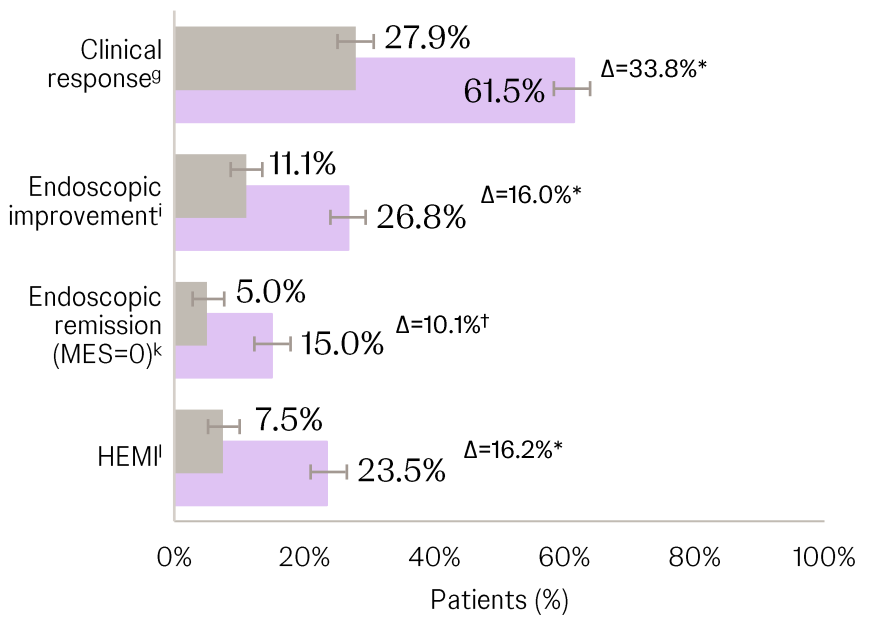


Primary endpoint at Week 44



99% (178/180) of patients in the combined TREMFYA® group who achieved clinical remission at Week 44 were corticosteroid-free for ≥8 weeks[3f]

Select secondary endpoints at Week 12



* = *P*<0.001 versus placebo

TREMFYA® (n=421)

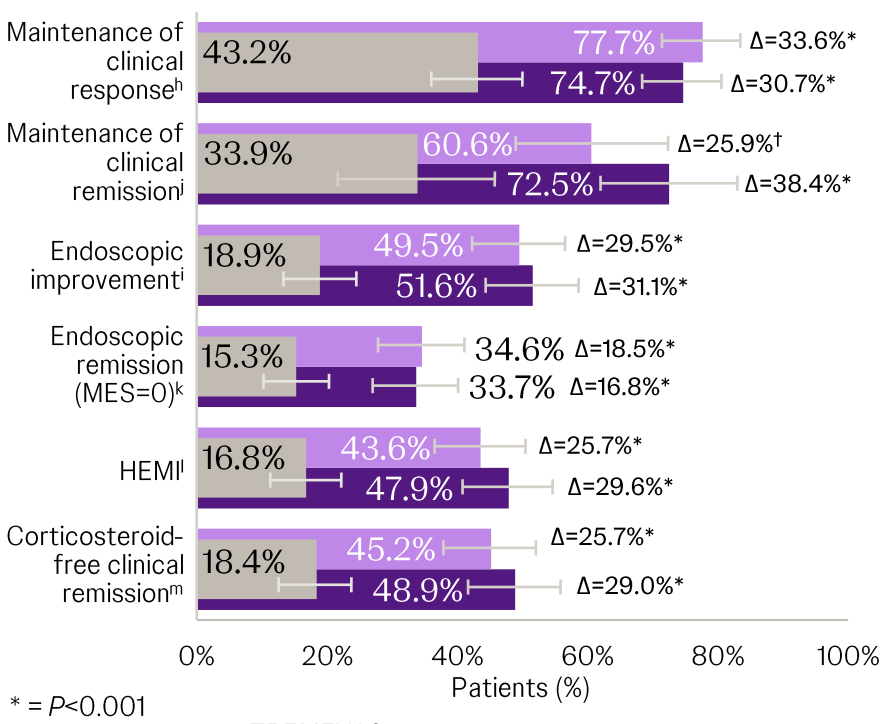
PBO (n=280)

† = Nominal *P*<0.001 versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

Symptomatic response through Week 12 (click for more info)

Select secondary endpoints at Week 44

Over 1/3 of patients were in complete endoscopic remission (MES=0) at Week 44



* = *P*<0.001 versus placebo

† = *P*=0.004 versus placebo

TREMFYA® 100 mg q8w (n=188)

TREMFYA® 200 mg q4w (n=190)

PBO SC (n=190)

Week 24 responders (click for more info)

Safety through Week 44

Summary of treatment-emergent adverse events through Week 44[5]	Randomized Placebo	Randomized GUS 100 mg q8w	Randomized GUS 200 mg q4w
Analysis set: Randomized safety	192	186	190
Average duration of follow-up (weeks)	34.0	40.5	39.2
Average exposure (number of administrations)	8.2	9.9	9.6
Patients who died	0	0	0
Patients with one or more (n [%]):			
Adverse events (AEs)	131 (68.2%)	120 (64.5%)	133 (70.0%)
Serious AEs	1 (0.5%)	5 (2.7%)	12 (6.3%)
AEs leading to discontinuation	13 (6.8%)	7 (3.8%)	5 (2.6%)
Infections	63 (32.8%)	59 (31.7%)	59 (31.1%)
Serious infections	0	1 (0.5%)	2 (1.1%)

Adapted from Rubin D, et al. Digestive Disease Week 2024 presentation.

Respiratory tract infections occurred in ≥2% of patients treated with TREMFYA® and at a higher rate than placebo at Week 12 (8.8% versus 7.3%)[1n,o]

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Johnson&Johnson

TREMFYA® (guselkumab) for adults with moderately to severely active ulcerative colitis

QUASAR clinical program

TREMFYA® was evaluated in multicenter, randomized, double-blind, placebo-controlled induction and maintenance studies in adult patients with moderately to severely active UC.[1] The induction study (N=701) randomized patients 3:2 to receive TREMFYA® 200 mg IV q4w or placebo IV.[1,2] The maintenance study (N=568) took TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders[a] and rerandomized 1:1:1[b] to receive TREMFYA® 200 mg SC q4w, TREMFYA® 100 mg SC q8w, or placebo SC.[1,3]

Patient population[1]

Adults with moderately to severely active UC[c]

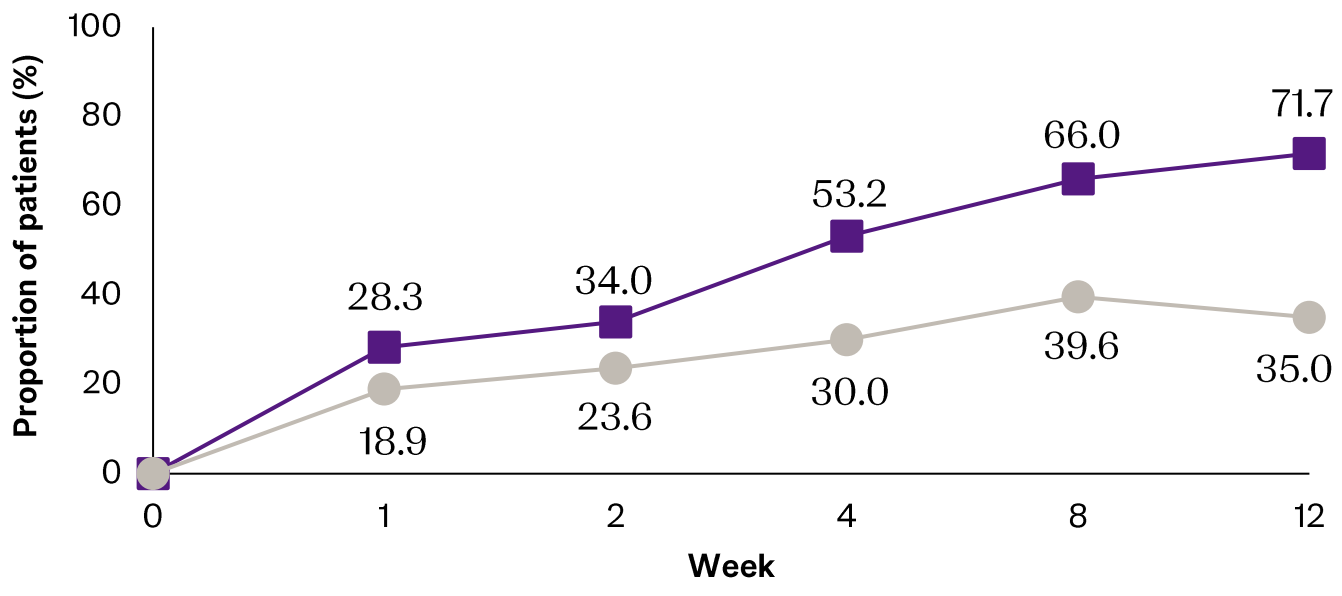
Prior inadequate response, loss of response, or intolerance to conventional or advanced therapy

49% of patients had prior inadequate response or intolerance to advanced therapy (TNFi, VDZ, or TOFA)

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC[1,2,4,5d]

Post hoc analysis: symptomatic response through Week 12

Separation from placebo in symptomatic response observed as early as Week 1*



Symptomatic remission was significantly greater with TREMFYA® vs placebo at the first study visit (Week 4, 23% vs 13%, *P*<0.001) and at Week 12 (50% vs 21%, *P*<0.001)

PBO IV (N=280)

TREMFYA® 200 mg IV (N=421)

Based on visual separation between TREMFYA® and placebo as early as Week 1. Symptomatic response data through Week 12 were *post hoc* analyses and not adjusted for multiplicity. No statistical or clinical significance can be made.

IV, intravenous; PBO, placebo.

Lichtenstein GR, et al. Oral Presentation #34. ACG 2023; October 20-25, 2023: Vancouver, BC.

* = *P*<0.001 versus placebo

TREMFYA® (n=421)

PBO (n=280)

† = Nominal *P*<0.001 versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

Symptomatic response through Week 12 (click for more info)

0% 20% 40% 60% 80% 100%

Patients (%)

* = *P*<0.001 versus placebo

† = *P*=0.004 versus placebo

TREMFYA® 100 mg q8w (n=188)

TREMFYA® 200 mg q4w (n=190)

PBO SC (n=190)

Week 24 responders (click for more info)

Safety through Week 44

Summary of treatment-emergent adverse events through Week 44[5]	Randomized Placebo	Randomized GUS 100 mg q8w	Randomized GUS 200 mg q4w
Analysis set: Randomized safety	192	186	190
Average duration of follow-up (weeks)	34.0	40.5	39.2
Average exposure (number of administrations)	8.2	9.9	9.6
Patients who died	0	0	0
Patients with one or more (n [%]):			
Adverse events (AEs)	131 (68.2%)	120 (64.5%)	133 (70.0%)
Serious AEs	1 (0.5%)	5 (2.7%)	12 (6.3%)
AEs leading to discontinuation	13 (6.8%)	7 (3.8%)	5 (2.6%)
Infections	63 (32.8%)	59 (31.7%)	59 (31.1%)
Serious infections	0	1 (0.5%)	2 (1.1%)

Adapted from Rubin D, et al. Digestive Disease Week 2024 presentation.

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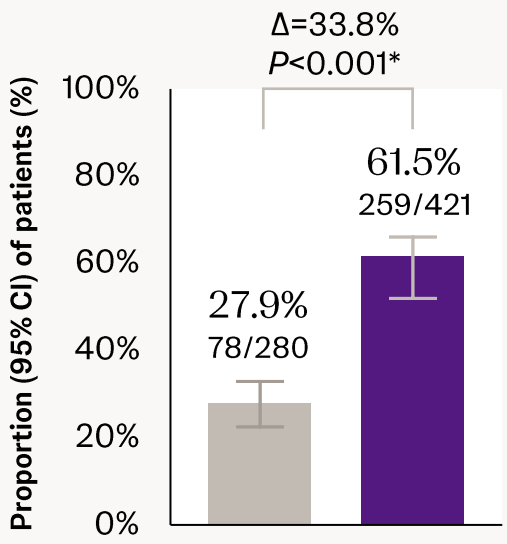
Clinical response at Week 12 or Week 24

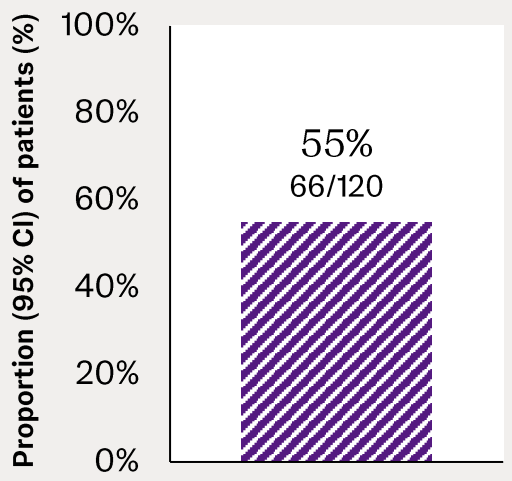
Placebo IV · GUS 200 mg IV · GUS 200 mg IV → GUS 200 mg SC[‡]

Clinical response at Week 12[1]

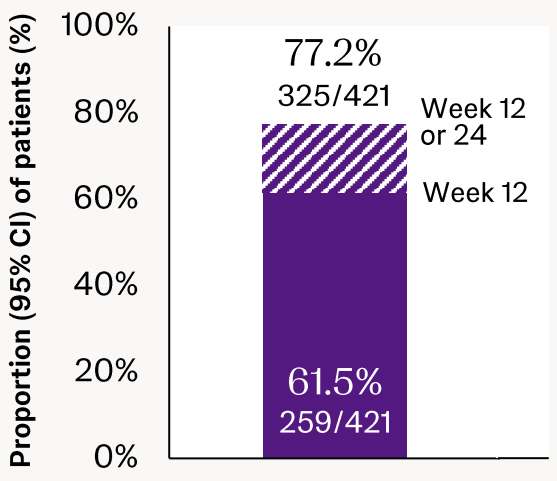


Clinical response at Week 24[2]

Among Week 12 clinical nonresponders to TREMFYA® IV induction who received additional TREMFYA® (guselkumab) SC treatment[†]



Cumulative clinical response at Week 12 or 24[2]



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*Adjusted treatment difference (95% CI) based on Cochran-Mantel-Haenszel method (adjusted for stratification factors: biologic and/or JAK-inhibitor failure status and concomitant use of corticosteroids at baseline). †Patients who had a prohibited change in UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 12 were considered not to have achieved the specified endpoints. ‡Patients received TREMFYA® 200 mg IV at Weeks 0, 4, 8 and then TREMFYA® 200 mg SC at Weeks 12, 16, and 20.

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